K002719

[TAB #12]

JAN 26 2001

Attachment #10

Summary of 510(k) Submission

A. INFORMATION

1. SUBMITTER'S

NAME:	**TILLOTSON HEALTHCARE CORPORATION**
ADDRESS:	**360 Route 101** **Bedford, NH 03110 U.S.A.**
TELEPHONE NUMBER:	**(603) 472-6600**
CONTACT PERSON:	**F.W. Perrella**
DATE SUMMARY PREPARED:	**August 2000**

2. NAME OF DEVICE

TRADE OR PROPRIETARY NAME:	**Formula One Powdered Examination Glove (with protein content labeling claim and Made from Allotex an enzyme treated natural rubber latex claim) medical glove.)**
COMMON OR USUAL NAME:	**Examination Glove**
CLASSIFICATION NAME:	**Examination Glove**

3. PREDICATE DEVICE IDENTIFICATION

NAME, NUMBER	**1. Formula One Powdered Examination Glove** K893901, K891939

4. DESCRIPTION OF DEVICE

a. HOW THE DEVICE FUNCTIONS:
Natural Rubber Latex films form a barrier to body fluids and bloodborne pathogens.

b. SCIENTIFIC CONCEPTS THAT FORM THE BASIS FOR THE DEVICE:
The latex rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

c. PHYSICAL AND PERFORMANCE CHARACTERISTICS SUCH AS DESIGN, MATERIALS AND PHYSICAL PROPERTIES:
Natural Rubber Latex is known to create a barrier to bloodborne pathogens and and body fluids. ASTM conforming tensile properties create a glove that is strong and flexible. The leaching process removes traces of chemical accelerants that may be chemically irritating. The glove is manufactured in accordance with the requirements of ASTM D3578-99 and ASTM D5151-99 requirements.

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASES OR CONDITIONS THAT THE DEVICE WILL ADDRESS

This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between patient and examiner. Examination gloves with protein content labeling are suitable in situations where healthcare worker or patient allergic sensitivity may be a factor.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

☐ **The modified product has a raw material change whereby the natural rubber latex is treated with proteolytic enzymes to digest natural rubber latex proteins compared to the predicate product.**

☐ **It is a powdered glove in the same way as the predicate product, but with a synthetic inner coating, protein content labeling, and Made from Allotex an enzyme treated natural rubber latex claim.**

B. IF THE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	PROPOSED	PREDICATE
	Powdered	**Powdered**
	(with protein content labeling and Made from Allotex an enzyme treated natural rubber latex claim)	
PERFORMANCE STANDARDS	**ASTM D3578-99**	**ASTM D3578-95**
WATER TIGHTNESS	**ASTM D5151-99**	**ASTM D5151-92**
RESIDUAL PROTEIN	**ASTM D5712-99**	

2. DISCUSSION OF CLINICAL TESTS

SPECIFICATION	PROPOSED	PREDICATE
SAFETY		
RABBIT IRRITATION	**Passes**	**Passes**
GUINEA PIG SENSITIZATION	**Passes**	**Passes**

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE
SAFETY EFFECTIVENESS, AND PERFORMANCE =/> PREDICATE PRODUCT

The Formula One, Examination Glove has been carefully compared to legally marketed devices in the 510(k). The data summaries indicate that the proposed product meets or exceeds acceptable scores for the predicate product in nonclinical tests, and satisfies the requirements for a safe and effective, Powdered (with protein content label labeling and Made from Allotex an enzyme treated natural rubber latex claim) medical glove.

Pursuant to 21 C.F.R. 807.87 (j), I, F.W. Perrella, Ph.D., Vice President R&D certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the V.P. R&D for TILLOTSON HEALTHCARE CORPORATION, and in reliance thereupon, the data and information submitted in this of the substantial equivalence of this device have been knowingly omitted from this Submission.

F.W. Perrella, Ph.D.
Vice President R&D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2001

Mr. Frank.W. Perrella
Vice President of Research & Development
Tillotson Healthcare Corporation
360 route 101
Bedford, New Hampshire 031105-5030

Re: K002719
Trade Name: Formula One Powdered Latex Examination Glove, with Protein Content Labeling Claim 200 Micrograms or Less and Made From Allotex™ an Enzyme Treated Natural Rubber Latex
Regulatory Class: I
Product Code: LYY
Dated: January 8, 2000
Received: January 9, 2000

Dear Mr. Perrella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002719

3.0 Indications for Use Statement: Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the Indications for Use statement.

INDICATIONS FOR USE

Applicant: Tillotson Healthcare Corporation

5 10(k) Number (if known):*

Device Name: Formula One Powdered Latex Examination Glove, With labeled Protein Content and Made from Allotex™ an Enzyme Treated Natural Rubber Latex Labeling claim (200 microgram or less)

Indications For Use:

The Formula One Examination Glove is "a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.". (21CFR 880.6250).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH Office of Device Evaluation (ODE)

Clin S. Lam

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K002719

Prescription Use _____ OR Over-The-Counter X
Per 21 CFR 801.109
(Optional Format 1-2-96)

For a new submission, do **NOT** fill in the 510(k) number blank.